TAB 9

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

THE CITY OF HUNTINGTON,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01362
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	
CABELL COUNTY COMMISSION,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01665
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	

BENCH TRIAL - VOLUME 14
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

MAY 20, 2021

Q. Okay. And then you multiplied that number by three?

A. The root number times three, yes.

Q. Okay. So, that's your initial triggering system? That's step one in your SOMS process, correct?

A. The threshold is the triggering, yes.

Q. So, Step 2, if you have a triggering event, you have to do something, right?

A. Yes.

Q. Yes, I'm sorry. It's next to you, too. I apologize.

A. It's over here.

Q. Does it matter --

MS. MAINIGI: Excuse me, Mr. Fuller. May I -- I think this is a different demo. Which demo number is this?

MR. FULLER: I'm sorry.

MS. MAINIGI: You're going to go back to Demo 02? Thank you.

MR. FULLER: Yes, ma'am.

BY MR. FULLER:

Q. All right. So, we have to do something if there's a triggering effect, correct?

A. Yes.

Q. And based on the way your system was designed, did it matter whether you were triggered just by a little bit or triggered by a lot?

A. Once there was a trigger, there was an analysis.

Q. So, let's -- for example, if we had a threshold that's 10,000 pills of oxycodone and someone goes over it by a hundred pills, it still triggers in your system, correct?

A. Yes.

Q. And you would still have to take action, right?

A. Correct.

Q. Same example, but let's change the numbers. 10,000 pill threshold, but they go over by 5,000 pills. It doesn't change at least this part of how the process works? You still have the triggering event and you still have to take action, correct?

A. Yes.

Q. Okay. Now, if you choose not to take action, can you cancel and report the order to the DEA?

A. We -- I don't know what you mean by if you choose not to take action. We always took an action to do an evaluation.

Q. Okay. So, your suggestion to the Court is that every order that triggers is going to have some sort of due diligence?

A. Yes.

Q. And that due diligence is going to be documented, correct?

A. That due diligence would be documented in the system.

Q. And when we're doing the due diligence, what we're

trying to do is to determine whether we can clear this order or whether we have to report the order to the DEA, correct?

A. Yes.

Q. So, let's go to Step 3. So, Step 3, if we have adequate due diligence that clears the order, whatever amount it is, it's your understanding that under your system you would then be cleared to ship the order?

A. Yes.

Q. If you conduct the due diligence and you cannot clear it, meaning you cannot validate the order, it's not likely to be diverted, then you have to -- you have a suspicious order that's not cleared and you have to block it and report it, correct?

A. Yes.

Q. Okay. Do you know how many suspicious orders you reported into Cabell or Huntington?

A. I do not.

Q. Do you know how many suspicious orders you reported into the State of West Virginia during your time? And I want to limit the questions. Let me go back for a second.

During your tenure, what we described as Chapter 2, from the end of -- December of '07 to September of '08 -- or to September of '12, do you know how many suspicious orders you reported into Huntington and Cabell County?

A. I do not.

order that broke a particular size, that -- in the analysis you could look at all of the orders below that to assess a pattern, assess a frequency.

And in doing so on a 30-day rotational basis, you were able as a pharmacist, member of the team, to analyze all of the additional characteristics; its size, unusual size, deviating substantially from a normal pattern, and unusual frequency.

So the system itself is a very broad, comprehensive system.

Q. And let me back up and maybe my question was a little unfair, so let's go back.

As to the triggering mechanism, being the threshold, that's based on volume in and of itself; correct?

A. The threshold -- the threshold is based upon the -- the threshold is based upon a number, a size.

Q. Okay. So my question pertains just to the threshold and the triggering event. That only measures volume; right?

A. The threshold itself in the way it's constructed assesses a volume analysis. But inside that volume analysis, because you are looking at specific orders for specific -- specific orders for specific customers, you are able to do in that analysis the deviating from an unusual frequency, unusual frequency, and the rest of --

THE COURT: I'm going to have to interrupt you.

I've got a technological breakdown here.

(Pause)

It's working. Yeah, that's fine.

BY MR. FULLER:

Q. So that additional analysis is what your pharmacist would do; correct?

A. The pharmacist team, yes, that is correct.

Q. And here if we go back to the PowerPoint, it says, "Reporting suspicious orders to the DEA does not relieve the distributor of the responsibility to maintain effective controls to prevent diversion."

And you agree with that; correct?

A. First of all, this is not my slide. I believe if you are looking to the correspondence that that statement does appear in DEA correspondences.

Q. My question is, as the one running the Anti-Diversion Control Program at Cardinal for the Chapter 2 time frame, do you agree with that statement?

A. Yes. The reporting of suspicious orders is not the totality of the obligation.

Q. And a registrant, such as Cardinal, has an obligation beyond just reporting suspicious orders; correct?

A. It does. The, the obligation is to maintain effective controls against diversion. And amongst, amongst others, you've got the security requirements that are associated

with the distribution centers. So, yeah, there are things beyond just that one particular regulation.

Q. So do you agree that shipping suspicious orders is not maintaining effective controls against diversion?

A. I would not agree. The, the obligation is to report suspicious orders. The, the regulation says develop a system, implement that system to report suspicious orders of controlled substances. That's the obligation.

Q. But you also have an obligation to maintain effective controls to prevent diversion; right?

A. In, in the CSA there is that requirement to maintain effective controls against diversion.

Q. And, and according to Mr. Mone, effective controls still means we can still ship out onto the streets, into pharmacies suspicious orders?

A. No, it does not.

Q. So we must not ship suspicious orders to prevent diversion?

A. Suspicious -- once a suspicious order is identified, that suspicious order is reported, is reported to DEA and not shipped to the customer.

Q. And, so, do you -- I'm a little confused now because what I'm trying to figure out, since it's obviously an issue in the case, is whether maintaining effective controls requires us to not ship suspicious orders.

Q. And all this is part of being vigilant as a distributor, as a registrant to ensure we're not over-supplying somebody; correct?

A. It is all part of the due diligence process to make a decision as to whether or not an individual customer would become a Cardinal Health customer.

Q. Now, could a customer refuse to provide some of this information?

A. If a customer -- could they? Yeah, a customer could refuse to provide some of that information. Then we would take that under consideration as to whether or not to open them up or not.

Q. Meaning that might be a red flag; right?

A. We would consider that a, a -- we would consider it amongst the totality of the circumstances as to whether or not we would open a customer and allow them to purchase medicines from us.

Q. And what about top prescribers? Would you obtain that information from them?

A. Initially because -- in the initial stages of where we were in the development of the program and because much of the, much of -- not the totality of, but much of the emphasis was on internet pharmacies, the top prescribers were an element of analysis.

Q. And then a determination is made as to whether to sign

on that customer?

A. That is correct.

Q. And who determines what the threshold is going to be initially for the customer?

A. It was -- the initial thresholds were determined based upon an analysis by the analytics team and the pharmacist team after they have made a determination that the information on the customer was sufficient to open up a customer.

Q. Now, let's still deal with new customers, but let's switch over to chains. Did chains go through a different process in on-boarding?

A. Chains did go through a different process in on-boarding.

Q. And was that controlled by your department or some other department?

A. It was still controlled by our department.

Q. And who had control of whether a chain was on-boarded?

A. Still our -- still our team had a -- had the decision as to whether or not a new chain would be added to, as a customer.

Q. And this important information that we've been talking about, would you get the same information from the chain customer?

A. Sometimes we did, sometimes we did not.

Q. Why would there be occasions where you would not?

A. The occasions where we would not were situations where the, the, the, the data either was not available because it was a, it was a brand new store, there was nothing there, you know, they put a new building in, and sometimes we would use the analysis of the characteristics of the chain in terms of whether it's a 24-hour store, where it was located to place them in the segmented categories that we may have had for that particular chain.

Q. Were there certain chains that wouldn't provide you information when requested; for example, CVS?

A. To the best of my recollection, whenever we requested information, we received the information from the chain in order to enable the, the, the pharmacist team to make a decision.

Q. And then on top of that, I think you stated in the past that you would determine what their SOMS system was; is that correct?

A. We would determine based upon the factors that we knew about, the new location, where they fit in terms of characteristics, recognizing that the, the chain itself had some fairly unique, you know, standard characteristics; 24-hour stores, you know, where they were located, et cetera, put those into the segmentation. And we would segment them and start their initial thresholds at that

2008?

A. Oh, yeah. At the beginning -- at the beginning of the implementation of the changes to migrate to this type of system, we were paper-based.

Q. Next Power -- next point says "Questionnaire sent to QRA by customer, the plausibility evaluation."

A. Yes.

Q. Is that where you're evaluating the basis of their explanation?

A. That is where the pharmacist team would take the information based upon their knowledge and experience, the pharmacist and analytics, to look at the data that was coming back and to make a decision what to do with that order.

Q. And this is verified by a site visit?

A. There, there were opportunities whereby the pharmacist team, in their evaluation, would say this is plausible, plausibility evaluation. If the order is not suspicious, let's go look at the pharmacy to see the rest of the story, the totality of the story, you know. And we would set up our investigatory team to go do a site visit.

Q. And this is all a process that has to be gone through when we have a triggering event to clear an order; correct?

A. Not necessarily. This process -- the, the verification by a site visit was not an absolute default. As I said

earlier in the last response, the pharmacist may determine that the order was okay, the plausibility piece. But in, in their professional decision, they wanted a site visit.

And, so, they would set up a site visit with the investigatory team. It didn't change the nature of their assessment of the order. It just said let's go to the customer for the rest of the story.

Q. This process that's gone through, we would see some of that documented in the due diligence file for that particular customer; correct?

A. In the early stages of the system, those -- the documentation would be on paper in a file. Later on, that information was retained in an electronic system.

The documentation was not the totality of the -- what was going on in the heads of the professionals that we were using. It may simply have been a summary analysis, a shorthand version of, say, yes, I've done my diligence and I've done the totality of the circumstances review and I've made a decision.

Q. But we're going to have the questionnaire -- we're going to have the response to the questionnaire. Any of that additional information is going to be compiled in that; correct?

A. Some of that information -- you know, the questionnaire more than likely would be there. Some of that information

would be retained.

However, depending upon the time frame and the circumstances, not every document is going to be in existence today 12 years later -- well, 11, however many years later we are -- on a paper system. Some of those paper systems were -- the records retention policy was two years and some of those paper documents don't exist any more.

Q. Let's go to Page 122.

THE COURT: Let me ask you a question that just occurred to me. And I'm sorry to interrupt the flow here and I may have missed it. But did DEA provide any guidance or have any input into how you determined your threshold requirements?

THE WITNESS: Absolutely none. The DEA -- the DEA said, "You built the system. It's your system and your responsibility," essentially. So they didn't, they didn't provide any of the substantive guidance on how to --

THE COURT: So you determined the way you established the threshold requirements completely on your own?

THE WITNESS: There -- so when counsel asked me the question about the multiplication times three, to the best of my recollection, there was a DEA public -- I forget what it's called -- Advisory Committee, Public Advisory

Committee whereby they came together and made some recommendations. We used that same kind of -- because it was on the DEA site, we sort of used it as a framework within which to make our decisions about thresholds.

THE COURT: I completely interrupted your flow there, Mr. Fuller.

MR. FULLER: You can interrupt any time, Judge.

THE WITNESS: You get to do that.

BY MR. FULLER:

Q. And the Court had a great question. The, the involvement of the DEA -- you referred to, I think, what's referred to as the chemical handlers; right?

A. Yes.

Q. And chemical handlers is designed based, I think you stated, on the Meth Act?

A. To the best of my recollection, yes.

Q. And it's designed to identify extraordinary orders of List I chemicals; is that right?

A. Yes, I believe that's accurate.

Q. So it's not necessarily applicable to controlled substances unless they contain List I chemicals.

A. It's not necessarily -- you're right. It is not necessarily applicable, but it does provide a reasonable, rational framework within which to begin a discussion or a thought process about how to develop such a system.

Q. And that system is designed, or the chemical handlers is identifying extraordinary sizes of List I chemicals; correct?

A. That is correct.

Q. Okay. Let's change to -- so the QRA evaluation --

A. Yes, sir.

Q. -- determination has to be made at Cardinal as to whether an order is plausible and suspicious or not plausible and suspicious; correct?

A. Yes.

Q. And it, it's determined -- if the order is not plausible and suspicious, you set out the process that's going to occur; correct?

A. Yes. And the only point that I would make note of is that the order was already blocked because it -- you know, in most instances because it had a threshold.

Q. It blocked at the triggering mechanization we looked at earlier; correct?

A. Yes, correct.

Q. And then the suspicious order has to be reported to the DEA; is that right?

A. Once you determine that it is suspicious, the order is reported to the Drug Enforcement Administration.

Q. Sales is notified as well; right?

A. That is correct.

Q. And who is Chris Anderson? Do you know?

A. Okay. I learned from the last time I'm going to read what it says down below. He is the Director of Operational Excellence and Quality Systems.

Q. There's always a good way to cheat a little bit, huh?

A. Yeah.

Q. All right. It says here -- you write to Chris, and this is October 1st of 2008, that, "I made a few changes to the slides and some information has changed a bit." Right?

A. Yes, sir.

Q. And you attached several documents -- well, actually, I think it's one PowerPoint presentation. Correct?

A. The documents, I believe, originated with Chris.

Q. Right. You're sending them back to him after you made some changes?

A. Yes, yes.

Q. And have you seen these slides before as well?

A. I undoubtedly have seen these slides before, but I don't recall them currently, you know. It's 12 years ago.

MR. FULLER: Your Honor, I would move into evidence Plaintiffs' 1930.

THE COURT: Any objection to 1930?

MS. MAINIGI: No objection, Your Honor, provided that the witness can corroborate a foundation. I note that there are some notes on the page in addition to the slides.

And the witness has testified that he's flipped through the slides. I don't know if he can corroborate the notes that are on the slides.

BY MR. FULLER:

Q. Mr. Mone, let me ask a question. Mr. Mone, when you went through this, were you reviewing the totality of the PowerPoint?

A. To the best of my recollection, I was reviewing my components of the slides.

Q. And you made edits to those?

A. Apparently, I did. What those edits were, I don't recall what they were.

Q. Sure. You don't have an independent recollection today of what edits you made?

A. Right.

Q. But according to your statement in the email, you made edits and then you sent it back?

A. Yes.

MR. FULLER: Judge, I would move for the admission.

MS. MAINIGI: Your Honor, I still don't think a foundation has been laid for the notes portion of the slides.

THE COURT: Did you make the notes, Mr. Mone?

THE WITNESS: I did not.

THE COURT: Do you know who did?

THE WITNESS: I do not.

MS. MAINIGI: I'm fine with admitting it without the notes.

THE COURT: Let's excise the notes and admit it without the notes. How about that, Mr. Fuller? Are you happy with that?

MR. FULLER: Judge, I think he would have reviewed it, but that's fine. I don't have any objection.

THE COURT: Okay. 1930 is admitted, but the Court will not consider the notes. They're not -- the notes are not admitted. The rest of the exhibit is admitted.

MR. ACKERMAN: Your Honor, --

BY MR. FULLER:

Q. Mr. Mone, turn to Page 18 of the document.

A. Yes, sir.

Q. This is the idea of the mentality behind your system, isn't it? First we identify; correct?

A. Correct.

Q. That's through our triggering system?

A. Right.

Q. Then we block, meaning we can't ship the order; right?

A. That is a component of the triggering system.

Q. Then we have to conduct due diligence. And if we don't surpass the due diligence threshold, meaning clear the

Q. Mr. Mone, did you use these to monitor how the system was functioning?

A. These were tools that were used by the team to make assessments of the program.

Q. And then, these are all based off the thresholds, correct?

A. These reports are based off of threshold, that is correct.

Q. Now, we talked about setting the thresholds earlier and you're setting them, at least initially, end of 2007, beginning of 2008, correct?

A. That was the initial thresholds setting process, yes.

Q. Before your arrival, Cardinal didn't use these type of thresholds, right? They used Ingredient Limit Reports?

A. Before I got there, Ingredient Limit Reports were being -- were done and when I got there, they were already -- the system was already in the beginning stages of making adjustments to an electronic system.

I don't recall how -- I don't recall how those initial orders, you know, that they were establishing in the immediate term before I got there were done.

Q. But you implemented this threshold system we've been talking about today?

A. I improved -- I improved the entire -- I would like to think I improved the entire system that was there.

Q. And so, when you devised how these thresholds were going to be set using the system we talked about earlier, subcategorizing the customers, then subcategorizing them on size, then determining an average and tripling it, what did you do to take into consideration that the company was in the throes of an opioid epidemic?

A. The considerations that we made were to take our assumptions that we were making in terms of where to place those thresholds and bounce those up against external experts to make certain that the assumptions that we were making were -- were appropriate.

Q. And then that led you to the conclusion that it was still a good idea to multiply the average by three?

A. Yes. When we sent -- when we sent it out and had external folks look at the process, they came back with an assessment with the assumptions that we were making were appropriate.

Q. Now, we've talked about the thresholds. We've talked about that they're tracked. You guys had a -- and I said you guys. I'm sorry. Cardinal had an electronic system for tracking these thresholds and I think you testified earlier these were kept in the normal course, correct?

A. That is correct.

Q. You also tracked threshold changes in the normal course; is that right?

A. Through system track changes, we did.

Q. You had access to these systems?

A. I did have access to the systems, yes.

Q. As well as the rest of your team; is that right?

A. Absolutely.

Q. Now, not only with threshold changes, but threshold events. We see here that on certain months, for example, May of '08, we have the 421 threshold events. Those are tracked, as well, correct?

A. Which document are you referring to?

Q. I'm sorry. I'm on 7509, the one that has your e-mail attached to it.

A. Okay, thank you. 7509? And what was your statement -- question?

Q. Yes, sir. I'll ask the question again. Where we have June of '08 the 421 threshold events --

A. Yes.

Q. Those are also tracked within Cardinal's system; is that right?

A. Yes, they were.

Q. Those were also accessible by you?

A. Pardon?

Q. You also have access to those?

A. I did.

Q. No longer?

A. Correct.

Q. You did at the time?

A. Correct.

Q. Your team had access to those?

A. They did.

Q. It's something that your department would use on a regular basis in maintaining the anti-diversion system, correct?

A. Yes, they would.

Q. You also tracked all the suspicious orders that were reported, correct?

A. Yes, we did.

Q. You could look up and see how many suspicious orders were reported in certain geographic areas, as well as particular pharmacies; is that right?

A. Yes, we could.

Q. You had access to that system?

A. Undoubtedly, I had access to the system. I'm not sure I knew the ability to extract that information out of the system.

Q. That may be something that you asked one of your other team members --

A. Yes.

Q. -- to pull for you; is that fair?

A. Yes.

Q. Okay.

MR. FULLER: Your Honor, at this time, I would like to move in P-14294. We disclosed this last night and there was no objection.

MS. MAINIGI: We have no objection, Your Honor, to its admission. Obviously, we can -- if it's something he's going to question the witness on, we can take that piece of it up as it goes, but we have no objection to its admission.

THE COURT: Okay, it's admitted.

PLAINTIFF EXHIBIT P-14294 ADMITTED

MR. FULLER: Your Honor, I'm going to test my luck. I'm going to move for admission of P-44275.

MS. MAINIGI: Same position, Your Honor.

THE COURT: Admitted.

PLAINTIFF EXHIBIT P-44275 ADMITTED

MR. FULLER: And I would move for admission of P-42071.

MS. MAINIGI: One moment, Your Honor.

THE COURT: Yes.

(Pause)

MS. MAINIGI: Same position, Your Honor.

THE COURT: All right. It's admitted.

PLAINTIFF EXHIBIT 42071 ADMITTED

BY MR. FULLER:

Q. Mr. Mone, a moment ago when we were talking about the

design of the thresholds and taking into consideration the epidemic, you mentioned relying on third-party experts. What third-party experts would that be?

A. Well, we subjected our SOM program to Deloitte. We subjected elements of it to IBM Watson. There were improvements that we looked at and we submitted to a Ph.D. at Ohio State. There may, in fact, be more, but those are the three I can think of right now.

Q. Now, let me try to inquire on those. The submission to Ohio State came further on in the system, correct?

A. It did.

Q. The submission to Cegedim Dendrite was earlier on in the system, correct?

MS. MAINIGI: Objection. I don't think that is the testimony. I don't think Mr. Mone said Cegedim Dendrite. He said IBM Watson, he said Deloitte, and he said Ohio State.

THE COURT: Sustained.

BY MR. FULLER:

Q. Mr. Mone, I'm handing you what's marked for identification purposes as Plaintiffs' Exhibit 80. Have you seen this document before?

A. I have not.

Q. You had -- do you have any understanding of what this Investigative Demand Committee Report would be?

A. No.

Q. Sure.

A. May I -- may I make a correction?

Q. Sure.

A. Because I'm just not certain. I may actually have seen parts of this document in a prior deposition, but I haven't seen the document, the whole thing.

Q. Fair enough. So, you may have recollection of this document from a prior deposition; you don't remember seeing it during the course of your employment?

A. I do not. Do not.

Q. Do you remember whether in the beginning of -- end of 2012, beginning 2013, whether there was an investigation conducted related to the SOMS systems at Cardinal?

A. I recall a -- for lack of a better term, I recall an internal -- an internal inquiry into the Suspicious Order Monitoring Program.

Q. And were you interviewed related to that process?

A. To the best of my recollection, I was.

Q. Do you believe some of your team members may have been interviewed in that process?

A. Undoubtedly, they were, more than likely.

Q. And was that looking at and reviewing the SOMS system in place and any potential changes that may need to be made?

A. I would assume that's what they were looking at.

THE COURT: Yeah.

(Pause)

MR. FULLER: Your Honor, I'll pass the witness.

THE COURT: All right. Thank you, Mr. Fuller.

Ms. Mainigi?

MS. MAINIGI: Yes, Your Honor.

Mr. Simmons, are we ready to go or do you need a couple of minutes?

We probably just need a couple of minutes of transition, Your Honor, if that's okay.

THE COURT: Okay. Let's just -- I'll stay on the bench.

MS. MAINIGI: Sure.

THE COURT: And you can go ahead and do it that way.

MS. MAINIGI: Thank you, Your Honor.

MS. MAINIGI: Mr. Simmons, are we ready?

Good afternoon, Mr. Mone.

THE WITNESS: Good afternoon.

Mr. Simmons, let's go ahead and put Demonstrative 2 up.

CROSS EXAMINATION

BY MS. MAINIGI:

Q. I just want to take a few minutes and review your background before you came to Cardinal, Mr. Mone.

A. Okay.

Q. Does this demonstrative accurately reflect your qualifications and background before you came to Cardinal Health?

A. It is a summary of my background, yes.

Q. And can you describe for us your educational background, please?

A. So, educationally, I attended the University of Florida. I graduated from there twice, once from the College of Pharmacy and once from the College of Law.

Q. Could you pull the microphone a little bit closer? I'm having a little bit of a hard time.

A. Okay. Is that -- is that better?

Q. Yes. That's wonderful.

A. Sorry.

Q. Have you worked as a practicing pharmacist?

A. I have.

Q. And did you also work for the Florida Board of Pharmacy?

A. I did.

Q. Can you tell us at high level what you did for the Florida Board of Pharmacy?

A. When I went to work for the Board of Pharmacy, I was a prosecutor for the Florida Board.

Q. And are there particular types of actions you prosecuted?

A. The -- the actions that were found to have probable cause. So, I would prosecute at the administrative law level pharmacists and pharmacies over allegations of deviations from the standard and statutes for the practice of pharmacy and pharmacists.

Q. And did that work give you experience in pharmacy regulation?

A. It did.

Q. And then, did you later work for the Florida Attorney General's Office?

A. I did.

Q. And describe for us what you did there.

A. I served as the General Counsel for Administrative Regulatory Boards, the Board of Osteopathic Medicine, Veterinary Medicine, Podiatric Medicine, and I also served as an Assistant on the Board of Medicine's Probable Cause Panel.

Q. And did you have occasion in that role to address issues related to opioids and other controlled substances?

A. I did as it related to those practitioners who were licensed in those particular fields.

Q. After the Florida AG's office, what was your next role?

A. I was -- I was voted, I was elected, I'm not sure what the right term is. The Kentucky Board of Pharmacy decided to hire me as their Executive Director.

Q. Tell us about that role. What did you do there?
A. For -- I was the Chief Administrative, Chief Executive, Chief Operating Officer of the state body that is known as the Board of Pharmacy.
Q. Now, in that Executive Director role, did you take any steps related to the prevention of the misuse of prescription medications?
A. Yes.
Q. Can you describe that for us, please?
A. Sure. While I was the Executive Director of the Board, in conjunction with the Cabinet for Health -- the Cabinet for Drug Services, the title I may have messed up, but at the instance of the Attorney General, Drug Control and the Board of Pharmacy worked on the establishment of the Prescription Monitoring Program in Kentucky.
Q. And what was the Prescription Monitoring Program that you worked on?
A. It's called KASPER and it was an all-schedule electronic reporting system that was implemented in Kentucky.
Q. And what was the goal of that Prescription Monitoring Program?
A. The goal of the -- at least as far as I could determine, the goal of the Prescription Monitoring Program was to provide a tool so -- to the practitioners, those who

wrote prescriptions, as well as those who dispensed prescriptions, to obtain a more full picture of the patient's use of controlled substances.

Q. And when you say practitioner, are you referring to prescribers?

A. Yes. Practitioners who have the authority to prescribe, yes.

Q. And who had access to this system that you helped with?

A. The practitioners, the prescribers, the dispensers, Drug Control themselves and I'm --

Q. Did wholesale -- I'm sorry.

A. And I'm sure whoever else was in the statute that said that they could have it. I just don't recall all the rest of the folks.

Q. Do you recall whether wholesale distributors had access to this program?

A. They did not. The program contains protected health information and wholesalers do not have access to the information.

Q. Besides the Kentucky Board of Pharmacy, can you describe other positions that you've held related to pharmacy?

A. Yeah. On the slide, it reflects that I was a member of the Ohio Board of Pharmacy. I served two terms there as President of the Board. I suspect you can look at my career

and say I tried to spend most of my career in public service.

And then the last bullet there is the National Association of Boards of Pharmacy where I -- as a -- as the Executive Director of the Kentucky Board of Pharmacy, I was elected to the Executive Committee of NEVP, but probably more significantly for me, is that for more than 20 years, I have served on the multi -- the Multi-State Pharmacy Jurisprudence Exam Review Committee.

Q. And what does that committee do?

A. It's the committee that puts together the law exam that every pharmacist in the country takes in order to get a license to be a pharmacist or to reciprocate from state to state.

Q. Thank you, Mr. Mone.

MS. MAINIGI: Now, we can go ahead and take that down, Mr. Simmons.

BY MS. MAINIGI:

Q. You spent some time with Mr. Fuller just setting the stage in terms of the timetable that you were -- the time period that you were at Cardinal Health running the Anti-Diversion System; do you recall that?

A. I do.

Q. And I think you told us that Mr. Steve Reardon came before you in terms of running the Anti-Diversion Program;

is that right?

A. It is.

Q. And then Mr. Todd Cameron came after you in terms of running the Anti-Diversion Program at Cardinal, correct?

A. He did.

Q. So, when you arrived in December, 2007, you said that the Cardinal Health Anti-Diversion Program was in the process of changing; do you recall that?

A. I do.

Q. What was your understanding of why the Cardinal program was changing in that time period?

A. My understanding of the basis for the change was that Mr. Reardon had attended a DEA Industry Conference a few months earlier and came back and began the development of the electronic -- the electronic component of the Suspicious Order Monitoring System.

Q. Now, what is your understanding of what happened at the conference?

A. My understanding of what happened at the conference was that a competitor had presented in conjunction with the DEA and explained their new electronic system for reporting suspicious orders and that the expectation of the DEA had changed relative to when Suspicious Order Reports would be sent to DEA.

Q. Was that competitor AmerisourceBergen?

A. It was.

Q. And do you recall whether that conference was in that September, 2007 time period right before you arrived?

A. Yeah. It was -- it was shortly before, so September is probably right.

Q. And with respect to the DEA expectations that you understood as you came in and took over the Anti-Diversion System, you mentioned the electronic system. Were there any other components that you're recalling got -- that Mr. Reardon brought back for implementation?

A. I call it the three prongs of what we did, which was Know Your Customer, electronic monitoring and investigations.

Q. Those were the three prongs that Mr. Reardon brought back?

A. To the best of my recollection, that's what were brought back.

Q. And if I could ask you to bring that a little bit closer to you. Still having a little bit of difficulty.

A. I'm sorry.

Q. That's better. Thank you.

Now, when you arrived in December, 2007, Cardinal Health was in the process of building out a system consistent with the new expectations of DEA?

A. I would say that's a fair statement.

Q. And you were charged with assisting an implementation of those changes?

A. Yes, I was.

Q. Now, did you come to understand whether there was any discussion at the conference about whether suspicious orders should be shipped?

A. I did.

Q. And what was your understanding?

A. That suspicious orders were not to be shipped to customers.

Q. Did you understand that that expectation was the same or different than it had been before?

A. That it was different.

Q. In your understanding, was there a statutory or regulatory requirement to not ship suspicious orders?

A. Given that the statutory reference to suspicious orders hasn't changed since, from what I could tell back then and what I understand to be the current language, since the language itself hasn't changed, it had to be a change in expectations.

Q. A change in expectations by the DEA?

A. Correct.

Q. Now, after you became the Head of Cardinal Health's Anti-Diversion Team, did Cardinal Health receive any letters from the DEA about their new expectations?

never changed, it had to be in compliance.

MR. ACKERMAN: Your Honor, I object on the ground that I --

THE COURT: One lawyer.

MR. ACKERMAN: I'm objecting for the City of Huntington, Your Honor.

THE COURT: Oh, okay. I'm sorry, Mr. Ackerman.

MR. ACKERMAN: Yes. We've switched now, so my microphone is back on. Object to that -- I think the witness's answer stated a legal conclusion. The question was a yes or no question, but the -- but in explaining the answer, the witness stated a legal conclusion. So, I'd object on that ground and move to strike.

THE COURT: Well, it's his understanding of what the situation requires. I'm going to overrule that and let him answer.

BY MS. MAINIGI:

Q. Now, let me -- we'll cover some changes, Mr. Mone, specific changes that you made going forward, but let me ask you, besides the changes that got made at the end of 2007, beginning of 2008, while you were Head of Anti-Diversion, was this the only time that Cardinal Health made changes to its system?

A. No. We were engaged in a continuous improvement process the entire time I was there.

Q. Now, do you recall Mr. Fuller asking you some questions about this 2008 settlement with the DEA?

A. I -- I vaguely recall them, yes.

MS. MAINIGI: Your Honor, as you know, we have objected to a discussion of that based on geographic scope and we retain our objection to that, but I am going to ask a few questions since Mr. Fuller was allowed to ask questions and we don't waive --

THE COURT: You may ask questions without waiving the objection.

MS. MAINIGI: Yes, Your Honor. Thank you.

THE COURT: That's fine. The objection will be preserved.

BY MS. MAINIGI:

Q. Around the same time that you took your position at Anti-Diversion at the end of 2007, did the DEA begin enforcement actions related to certain Cardinal Health Distribution Centers?

A. Yes.

Q. Now, in terms of timeline, if I represent to you that the ABDC Conference was September 2007, do you recall when the first immediate suspension order against a Cardinal Health Distribution Center occurred?

MR. FULLER: Objection, foundation, Judge.

THE COURT: Overruled. If he remembers, he can

answer.

THE WITNESS: To the best of my recollection, it was -- it was towards the end of November of 2007.

BY MS. MAINIGI:

Q. And was that the Auburn-Washington State facility?

A. Auburn was the first one, yes.

Q. And then were there two more in December, the month that you arrived?

A. Yes.

Q. And were those Lakeland, Florida and Swedesboro, New Jersey?

A. Yes. Swedesboro on my 50th birthday.

Q. Happy birthday.

A. Thank you.

Q. Was there also an Order to Show Cause in January, 2008?

A. I do not recall whether it was December or January, but I do recall an Order to Show Cause.

Q. And do you recall that was Stafford, Texas?

A. It was Texas.

Q. And each of those four distribution centers, Mr. Mone, had a separate registration with the DEA; is that correct?

A. They did, yes.

Q. And do you recall generally what type of pharmacies were involved in the 2008 DEA action?

A. They were predominantly what in the literature and the

DEA language were called internet pharmacies.

Q. To your recollection by this point in time, had Cardinal Health taken measures to ensure that none of its customers were acting as internet pharmacies?

A. Yes.

Q. Now, do you recall around that time how many distribution centers Cardinal Health had approximately?

A. I know that there were more than 20. I don't recall the specific number.

Q. And do you recall any allegation in this point in time, the end of 2007, beginning of 2008, against the Wheeling, West Virginia Cardinal Health Distribution Center?

A. No. I don't believe there was anything ever about Wheeling.

Q. And, to your knowledge, did any of the distribution centers at issue in the 2008 enforcement actions ship controlled substances to West Virginia?

A. To pharmacies in West Virginia?

Q. Correct.

A. No.

Q. And I think you've already testified that by the time you got some of these enforcement actions, Cardinal Health had already begun to make changes to its Suspicious Order Monitoring System?

A. Yes, it had.

A. Sure. He held onto the compliance officers, which is why you see only a dotted line to me. They actually are -- they're actually a solid line in to Steve.

Q. And you meant -- I'm sorry. Go ahead.

A. And Steve handled the Distribution Center licensing and security and the other components of the Distribution Center.

Q. So, what do the compliance officers do at the distribution centers?

A. Well, they're -- a lot of things. They're responsible for the cage and vault. They're responsible for licensing. They're responsible for maintaining the on-site records. They're responsible for communicating to -- to anti-diversion. And they're responsible to communicate up to Steve.

Q. Now, I see underneath you is Know Your Customer and I know that's a component of the system going forward, but can you describe why it's on the org chart?

A. Yeah. We -- what we did was, you know, as I indicated before, any good system is a PPT, people, process, and technology. And so, we took the components of the system, grouped individuals into areas of excellence, and placed them in the system so that the Know Your Customer folks or the intake folks, the Know Your Customer analyst folks that worked with the pharmacists.

Q. So did -- did the Know Your Customer folks evaluate and conduct diligence on new customers?

A. They did.

Q. And also existing customers?

A. They did.

Q. And were there -- there were questionnaires associated with that process? Did they fill those questionnaires out?

A. They did not fill the questionnaires out.

MR. ACKERMAN: Your Honor, a leading objection to the last question.

MS. MAINIGI: I'm just trying to move this along, Your Honor.

THE COURT: Yeah, overruled. We need to get through this and I don't see any harm to the question and then the answer.

THE WITNESS: The answer is they didn't fill it out. The customers filled it out.

BY MS. MAINIGI:

Q. What did the Know Your Customer folks do with the questionnaires?

A. They took it and where there -- as I indicated to counsel this morning, where there were objective ways of assessing what the customer provided, they would look those up, you know, licensure, and make sure that the licensure was right, and the objective data that they could find, and

then they would pass that on to the pharmacist.

Q. Then there is electronic order monitoring and pharmacists. And I know you referred several time to pharmacists with Mr. Fuller. Can you describe the role of those individuals?

A. These pharmacists were, as Mr. Fuller and I had the unfortunate discussion about pharmacists being -- these are our pharmacists who were assessing -- were doing the assessment of both the data that was provided through the Know Your Customer piece, as well as doing the evaluation of the threshold events.

Q. And then there's an Investigations Team. What did they do?

A. When the pharmacist made a request for additional information, the pharmacist would send it over to the Investigatory Team, who would then do a site visit -- to do a site visit of the pharmacy and those -- the boxes are our folks and we had additional -- and we talked about it earlier. We had the additional consultants that would go out and do those inspections.

Q. And then the Analytics Team, what did the Analytics Team do?

A. The Analytics Team was the team that produced the data that Mr. Fuller provided to me earlier and would work with the IT Team to -- to build the analytics capability.

Q. Now, as a wholesale distributor, is it fair to say Cardinal Health supplies a lot of products beyond opioids to its customers?

A. Yes. We're a full -- full line -- Cardinal Health is a full line pharmaceutical wholesale distributor.

Q. What are the other types of products at a very high level that Cardinal Health provides?

A. Very high level, your asthma inhalers. You know, your hospital supplies we provide from -- oh, from Band-Aids to specialty medications in the distribution channel.

Q. As a wholesale distributor, does Cardinal Health develop opioids?

A. It does not. It is not a manufacturer.

Q. Does it seek approval from the FDA to market opioids?

A. It does not.

Q. Does Cardinal Health develop or conduct clinical tests on the risks and benefits of opioids?

MR. FULLER: Object to form. Foundation.

THE COURT: Overruled.

THE WITNESS: To the best of my knowledge, we don't have any clinical folks that do that.

BY MS. MAINIGI:

Q. We've talked about the Closed System of Distribution. Can you describe what the Closed System of Distribution means?

meeting their corresponding responsibility, and then prepares it and dispenses it to the patient.

Q. So, if no patient comes in with a prescription to a pharmacy, what happens to the medication that the pharmacy ordered from Cardinal Health?

A. It sits on the shelf.

Q. And does that apply to all medications or just controlled substances?

A. Everything. You know, any legend drug, any -- let me -- I don't want to have definitions of legend drugs. Any prescription item first requires the patient to present a valid prescription to the pharmacist.

Q. Now, within this Closed System were quotas set by DEA as to the nationwide amount of opioids that could be produced?

A. Yes. And that applies to the manufacturer of the product, the quotas.

Q. And, to your knowledge, did Cardinal Health ever ship in excess of the DEA quotas?

A. It would be impossible for Cardinal Health to ship in excess of the quota.

Q. Why is that?

A. Well, because Cardinal Health is not -- first of all, the easy answer is Cardinal Health is not the only distributor. And there are no dosage -- there are no

amounts above what the DEA quota is that can be manufactured, so no one could distribute more than what the quota was.

Q. To your knowledge, did Cardinal Health ever ship to a pharmacy in Cabell or Huntington that was not registered with the DEA and licensed by the State of West Virginia?

A. To the best of my knowledge, we would not ship to any customer that was not registered by the State or the -- in the jurisdictions where the state required controlled substance registration and a DEA registration.

Q. And, to your knowledge, did Cardinal Health ever ship prescription opioids to a pharmacy in Cabell or Huntington that Cardinal Health knew or should have known was dispensing for a purpose other than to fill legitimate prescriptions written by doctors?

A. No.

Q. Now, when it comes to some of the reporting that Cardinal Health does to the DEA, is there reporting called ARCOS that you're familiar with?

A. Yes.

Q. Can you describe what that is?

A. Well, firstly, that -- the ARCOS reporting vault fell under Steve.

Q. Steve Reardon?

A. Steve Reardon, yeah. He's not there anymore, but Steve

Reardon. That's the component of that security and what have you that Steve did on the QRA side.

But the ARCOS Report is a report that is required to be submitted by -- I think it's manufacturers and distributors for all schedule Is, all Schedule IIs, and narcotic IIIs.

Q. So, for every single pill, Mr. Mone, the controlled substance that Cardinal Health shipped, did the DEA know who it shipped to?

A. Ultimately, DEA would know -- be able to know that information. It directly gets every month the ARCOS Reports which would -- now, mind you, we don't have any Schedule Is, but it's all Schedule IIs and Narcotic IIIs.

Q. And would the DEA know when that shipment occurred?

A. Yes.

Q. At any point during your time with Cardinal Health's Anti-Diversion Team from 2008 to 2012 did DEA inform Cardinal Health that it believed its shipments to Cabell County or Huntington were excessive?

A. No. There was no communication from DEA with regard to that.

Q. At any point during your time with Cardinal Health's Anti-Diversion Team from 2008 to 2012 did DEA inform Cardinal Health that its shipments to any particular pharmacy in Cabell County or Huntington were excessive?

A. No, they did not.

MS. MAINIGI: Your Honor, I'm about to change sections. Would now be a good time for our break?

THE COURT: Yes. Let's take about a ten-minute break here.

(Recess taken)

(Proceedings resumed at 3:40 p.m.)

THE COURT: Mr. Mone, you can come on back up, sir.

BY MS. MAINIGI:

Q. Welcome back, Mr. Mone.

A. Thank you.

Q. During the time that you worked at Cardinal, were you provided the resources necessary for the Anti-Diversion work that you led?

A. Yes.

Q. And during your tenure did the Anti-Diversion staff grow?

A. It did.

Q. Let's walk through the main components of the Suspicious Order Monitoring System that you helped to design and lead.

Demonstrative 5, Mr. Simmons, which counsel has no objection to, Your Honor.

BY MS. MAINIGI:

Q. So let's start with the Know Your Customer

component. I think you've talked about that a bit with Mr. Fuller, but did that part of the system involve gathering information about new customers?

A. It did.

Q. And, and how did that work? Describe it to us at a high level.

A. Well, the customer process was a holistic process that involved all of the Cardinal Health team members. It involved the sales folks that were at the, that were at the customer. It involved merchandisers. It involved the, the questionnaire. It involved the assessment of the answers on the questionnaire. The compliance officers could on occasion, and would on occasion, go to do ride-alongs with the, the folks. So we built a program that was, you know, holistic.

Q. And what did you do with the information that got gathered as part of Know Your Customer?

A. Well, in the initial stages, it was paper and we kept that paper and it was used by the pharmacists in their evaluations.

Q. Now, after a new customer was on-boarded, did the Know Your Customer process continue?

A. It did. It was a continuous -- you know, customers changed. Things changed with regard to the business. So it was a continuous process.

Q. The second component of the system, Electronic Order Monitoring, can you describe that part of the system, please?

A. Well, that was the technology component of the system whereby the, the system -- there's a warehouse management system which -- there's a warehouse management system that -- in which the orders are placed. And as a module on top of and alongside it, there was the Electronic Order Monitoring component that reviewed those orders that came in.

Q. And this is where the thresholds are that you spoke to Mr. Fuller about?

A. Yes.

Q. And can you describe -- I know it's a very elaborate process in terms of setting the thresholds, but at a high level can you describe the threshold process?

A. Yeah. The threshold process was a process whereby we took the totality of the circumstances that we knew and the characteristics of the pharmacy and the description of the patients that they treated, put, put that into a -- put that into the thought, put that into the thought process and made an evaluation of the type of customer that they were, segmenting the classification that they were, whether they were a retail pharmacy or a hospital or a chain pharmacy, and then sub sub-setting them into sizes.

Q. So were there individualized thresholds for each pharmacy customer?

A. There were individual thresholds for each pharmacy customer over -- well, even the initial one was individualized for that pharmacy, but it was individualized in a, in a bucket. And then over time, it became even more customized.

Q. And what would the categories of information that went into or were considered in setting a threshold?

A. Well, we looked at their prior, prior history if it was available. We looked at the characteristics of the pharmacy because like a Hospice pharmacy is going to look totally different than a psych pharmacy which is going to look totally different than a compounding pharmacy.

And they all may be retail independents, but their individual characteristics are going to differ in terms of how they are likely to order controlled substances, as well as every other drug.

Q. And over the years that you were there, did you modify or enhance your threshold setting methodology?

A. Yes. Over time we consistently looked at and built models to run the data against to adjust to be as precise as we could be given the limited information that we had.

Q. So if an order went above the threshold that was set for that particular pharmacy, what would happen next?

A. Well, the, the order would be held and the pharmacist would conduct an evaluation.

Q. Mr. Simmons, could we go back to the chart for a moment.

So the pharmacist in the Electronic Order Monitoring, those pharmacists would review the order then?

A. That is correct.

Q. And what -- to your knowledge, what are some of the things that that pharmacist or pharmacist team would do at that stage when an order had kicked to them?

A. Well, among other things -- and I can't tell you exactly what each pharmacist would do because there's a, there's a professional analysis that goes along with it.

But they would look at the Know Your Customer information that they had available to them. They'd look at the data that they had available to them in the system. They would look at the order. They would look at where the pharmacy is located.

They would look at -- they would look at, you know, things like their relationship to a hospital, the customer, where they were. It's the totality of the circumstances for, for that pharmacy.

Whatever we had and whatever they thought we needed, if they needed something else, they'd go to the Know Your Customer folks or they'd pick up the phone and call the

pharmacy, or they would try and get the information that was necessary to, to make an appropriate assessment.

Q. Mr. Simmons, could you put the other back up.

Now, when the pharmacist had, had an order that had kicked over to them, could their evaluation sometimes involve a visit to the pharmacy?

A. Yes.

Q. And could you describe that to me?

A. Well, a visit to the pharmacy would be a, a -- the investigative -- it's interesting. I'm going to say this. The investigative folks were the primary folks that were responsible for doing the investigations, plus the consultants that were investigators. And most of those were former DEA diversion investigators that we used.

Those folks would go in and they would use the framework of the Know Your Customer questionnaire as a basis for their inquiry when they got to the pharmacy.

So they did this like -- they, they did a pre-review of the data. And they would look at everything that we had. They would fill out a pre-review. And then the investigator would go in and get information to support or to support and affirm the information that they had, or if something had changed like, for example, they bought the files and -- you know, a chain pharmacy bought a file of a pharmacy that a pharmacy had closed, oh, there's, there's a change, and the

independent pharmacy bought the files of the pharmacy that closed, there's a change. How many prescriptions did you buy, what type of patients, all of that would go into it and then they would write a report.

Q. And, so, site visits may kick out of the electronic order monitoring process, but they might also be part of the investigations process?

A. Yeah, yeah. They, they weren't required to be done that way, you know. But both ways could result in, in, in an investigation.

Q. Now, who were the people who would conduct the site visit?

A. Well, when, when I got there, I'm a firm believer in cross functionality of folks. So the investigators that we hired -- we hired former police. We hired former -- we hired former Board of Pharmacy inspectors. We hired former Medicaid fraud unit inspectors. And that was the type of individual that I wanted, but I wanted a broad swath of them so that they could cross-train each other.

Q. And, so, those were some of the types of folks you hired as investigators who visited the pharmacy?

A. Yes.

Q. And the site visit process, was there a checklist or something that they worked off of?

A. Like I said, they used the Know Your Customer

questionnaire as -- used the Know Your Customer questionnaire as a framework. They did have their own document, but that's the framework that they used.

Q. Now, did you personally ever conduct site visits?

A. I did on occasion, rare occasions, but I did.

Q. Now, we've talked a lot about suspicious orders. At what point does a pharmacist in the Anti-Diversion group decide whether an order is suspicious?

A. They would decide that at the end of the evaluation that they made about the totality of the circumstances for that pharmacy and that order.

Q. And when a pharmacist made a determination that an order was suspicious, what did Cardinal Health do next?

A. The order was reported to DEA.

Q. Was it shipped?

A. No.

Q. To your knowledge, during your time at Cardinal Health, did the company ever ship a suspicious order?

A. No, it did not.

Q. I'm going to show you briefly a document that was previously admitted, Mr. Mone, and I don't think you've necessarily seen it, but I just want to ask you a couple of questions off of it.

Defendants' 1.

MR. FULLER: Judge, I would object to the

broadcasting until the witness has laid a foundation for it.

THE COURT: Okay.

MS. MAINIGI: It's an admitted document, Your Honor.

THE COURT: It's already been admitted, Mr. Fuller. Put it back up.

BY MS. MAINIGI:

Q. Now, Mr. Mone, what I'm putting in front of you is Defendants' Exhibit 1 which I will submit to you is the presentation that was provided at the September 11th, 2007, DEA conference by AmerisourceBergen. And I know you did not see this presentation at the time. I know you didn't attend the conference. I know Mr. Reardon did.

There are just a couple of components of the program that were put forward in this conference that I just want you to look at and comment as to whether they compare to the Cardinal system that you helped put together.

MR. FULLER: Judge, I'm going to object. She's going to question a witness who hasn't seen a document that you've prevented me from doing repeatedly about whatever is in the document?

MR. ACKERMAN: At a conference where the witness did not attend.

MS. MAINIGI: Your Honor, he, he's testified that

Cardinal modeled their system from this conference. Others did attend it and he's the primary architect of the new system at Cardinal.

I've represented that he has not seen the document before. I just want to walk through some of the generic components in the document.

MR. ACKERMAN: We maintain our foundation objection, Your Honor.

THE COURT: I'll sustain the objection.

MS. MAINIGI: We can take that down, Your Honor. Is it all right if I just run through a few of the components orally?

THE COURT: You can ask the questions and see where we go.

MS. MAINIGI: Okay. That's fine, Your Honor.

BY MS. MAINIGI:

Q. You can set aside, Mr. Mone, the document. I'm looking at Page 6 of the document. You described to us a Know Your Customer component just now to the Cardinal system; correct?

A. I did.

Q. And you also described an Order Monitoring Program type component and Electronic Monitoring Program component?

A. Yes.

Q. And did you describe to me an investigations component?

A. I did.

Q. And was there training also done at Cardinal Health related to Anti-Diversion?

A. Yes.

Q. Can you describe that for me at a high level?

A. At a high level we built modules, training modules that were a component of performance metrics for employees that involved reviewing the presentation and taking a test and requiring you to get 100 percent on the test before you could -- otherwise, you would be in this constant loop of watching the slides again until you got 100 percent of the answers correct.

Q. Who -- let me back up. Who received training on Anti-Diversion at Cardinal Health?

A. Well, to the best of my knowledge, I'm going to say just about everybody. What we did was -- Anti-Diversion was everybody's -- was everyone's responsibility. And the folks that I know that did were the, the sales folks, the sales op folks, my folks, and the distribution center employees. I know those folks did.

Q. And you were describing this 100 percent -- everybody had to take a test and get 100 percent on the test; is that right?

A. You got the question wrong, you went back through the slides again. And I think the testing folks were even mean

because when you got to the questions, they rearranged the answers so that you couldn't memorize that the answer was, the one you put was C and, you know, they were just sneaky.

Q. Okay. Now, your Know Your Customer due diligence, did Cardinal Health's program for Know Your Customer also include a new account set-up process, the new account questionnaires?

A. It did.

Q. And you discussed already the on-site visit. Is that fair?

A. Yes.

Q. Monthly sales limits. Did Cardinal Health have monthly sales limits for its customers?

A. I don't know what you mean by sales limits.

Q. Did Cardinal's system segment customers by size initially?

A. Yes, it did.

Q. And Cardinal Health called those thresholds?

A. Yes.

Q. During the time you were head of Anti-Diversion at Cardinal Health, did the Wheeling distribution center have a DEA registration that entire time?

A. It did.

Q. And in that time period, 2007 to 2012, did distribution centers have to periodically renew their DEA registration?

A. They -- they're required to periodically renew. I think it's a three-year license.

Q. So, to your knowledge, did DEA renew the Wheeling, West Virginia, distribution center license each time it applied?

A. I would submit to you that it did.

Q. Is it your understanding that if the DEA had ever had a problem with the Wheeling facility that they would have let you know about it?

A. I would like to believe that they would have.

Q. Is it fair to say that if the DEA had an issue with Cabell/Huntington pharmacies, they would have done something about it to your understanding?

MR. ACKERMAN: Objection, speculating.

THE COURT: Well, if he knows.

THE WITNESS: I, I would like to believe they would inform me.

BY MS. MAINIGI:

Q. To receive and maintain a DEA registration, did DEA have to determine that Cardinal Health had to provide effective controls to guard against diversion?

A. Yes.

Q. And did that involve physical security measures?

A. Yes.

Q. Did it involve suspicious order reporting?

A. Yes.

Q. Now, the physical security measures we haven't talked about much. But at a high level, what did the regulations require?

A. The regulations on physical security are rather extensive I think is a good word there. There's, there's the amount of rebar that has to be in the concrete and how wide the, the cage has to be -- it has to be set -- and who can have access to the cage and vault.

Those, those physical security requirements -- the cameras that you have to have. You know, there's a lot of extensive regulations on physical security.

Q. So there's a lot of details built into those regulations?

A. Oh, yeah.

Q. Now, as to the suspicious order reporting requirement, what did the regulations require?

A. The suspicious order -- it's a fairly small section that says that, that upon discovery, the, the -- you must, you must -- and I'm probably going to get this wrong -- design and implement the system to identify to the registrants suspicious orders of controlled substances. It was maybe 60 words and that's it.

Q. Now, did Cardinal Health report suspicious orders not just to the DEA but any other state regulatory body in West Virginia?

And, Your Honor, I'd like to move into evidence while we're waiting Cardinal 30.

THE COURT: Is there any -- you're moving into evidence 30?

MS. MAINIGI: Yes, Your Honor.

THE COURT: Is there any objection to 30?

MR. FULLER: No, Your Honor.

THE COURT: It's admitted.

THE WITNESS: May I amend my last statement?

BY MS. MAINIGI:

Q. Yes, please.

A. Not only was it our SOM people, but because this had to do with the, the database, this also applied to the individuals that maintained the database of customers.

Q. Thank you, Mr. Mone.

Please take a look at Cardinal 745. And could you identify this SOP for us, please?

A. This is the process to establish SOM threshold limits.

Q. And did you help put this together as well?

A. To the best of my recollection, I participated.

Q. And do you know who else assisted in putting this together?

A. It would have been the analytics people.

Q. And this is the process followed by who to set thresholds?

A. It is the framework and methodology when formulating thresholds by the analytics people and, of course, the pharmacists.

Q. And, to the best of your knowledge, were these procedures followed at Cardinal Health to set thresholds?

A. To the best of my knowledge, they were.

MS. MAINIGI: Your Honor, I'd like to move in Cardinal 745, please.

THE COURT: Any objection to 745?

MR. FULLER: No, Your Honor.

MS. MAINIGI: Could I have Cardinal --

THE COURT: It's admitted.

MS. MAINIGI: Thank you, Your Honor.

BY MS. MAINIGI:

Q. Cardinal 743. Could you identify that, please, Mr. Mone?

A. It is the SOP for threshold event review, self-verification; decision making and threshold outcome communication.

Q. So the last SOP related to setting the threshold. What related to the threshold does this SOP cover?

A. This covers the rest of the story with regard to what is done with reports.

Q. And, so, does this cover what happens if something kicks out of a threshold analysis or review?

A. Yes, it does.

Q. Does it -- is it one of the tools that gets used to help determine whether an order is reported as suspicious or not?

A. Yes, it does.

Q. And, to your knowledge, were these -- was this SOP followed at Cardinal?

A. To the best of my knowledge, yes.

MS. MAINIGI: Your Honor, I'd like to move for the admission of 743.

THE COURT: Any objection to 743?

MR. FULLER: No objection.

MR. ACKERMAN: No objection.

THE COURT: It's admitted.

BY MS. MAINIGI:

Q. Now, Mr. Mone, was there any involvement by the sales department in the threshold event review process?

A. No.

MS. MAINIGI: May I ask for Cardinal 740, please.

BY MS. MAINIGI:

Q. Coming back on sales for a moment while we hand this out, so sales, the sales staff did not participate in setting customer thresholds?

A. They did not.

Q. Did sales staff participate in raising or lowering

A. We did.

Q. Did Cardinal Health request ARCOS information from the DEA?

A. Yes, we did.

Q. Why?

A. Well, if you go back to the question you asked about who can see all of the data when there are multiple suppliers, there is a point in time when we requested the ARCOS data so that we would know not, not the "who" of the other suppliers, just the "what" and the volume of the "what" so that we could add that into our evaluation about the customer.

Q. Cardinal Health wanted to integrate into its evaluation process how much other distributors were sending to a particular pharmacy. Is that fair?

A. Yeah, the rest of the story.

Q. Did the DEA provide that information?

A. They did not.

Q. Why not?

A. To the best of my recollection, they claimed it was proprietary information.

Q. Did Cardinal just ask for that information once or multiple times?

A. Multiple times.

Q. Did Cardinal Health also ask the DEA to provide it with

any information that the DEA possessed indicating that any Cardinal Health customer was engaged in diversion so that Cardinal could cease distributing controlled substances to that customer?

A. To the best of my recollection, that was in a request to DEA.

Q. And did the DEA agree to let you know if it was aware of Cardinal Health's customers engaged in diversion?

A. I -- to the best of my recollection, I don't recall that there ever was a response to that request.

Q. We've talked a lot today about Cardinal Health SOM system and its components. Did Cardinal Health share the details about its Anti-Diversion system with the DEA?

A. Yes, it did.

Q. On more than one occasion?

A. More than one occasion.

Q. As part of that effort did you meet in early 2009 with Barbara Boockholdt of the DEA?

A. I did.

Q. And remind us, who is Barbara Boockholdt?

A. Barbara Boockholdt was -- maybe she was Chief of Regulatory, or she was Chief of the Policy Section at DEA and was our contact at DEA, at DEA headquarters.

Q. So this early 2009 meeting, describe that to me.

A. The early 2009 meeting was about -- I'd say it was

almost a week.

Q. The meeting was a week?

A. Pardon?

Q. The meeting was a week?

A. Yeah, more than, you know, I think approximately a week. Barbara and several other DEA diversion investigators came in to review our system.

Q. What do you mean by came in to review your system?

A. They came into Dublin and we sat downstairs in a, in a, in a room, in a meeting room and we went through our SOM system.

Q. And did that involve reviewing the SOPs and other policies related to the SOM system?

A. Yes, it did.

Q. Like the policies we looked at earlier today?

A. Yes.

Q. Did it involve reviewing how Cardinal Health set thresholds for its customers?

A. Yes, it did.

Q. Did you describe to Ms. Boockholdt and her colleagues how Cardinal Health was identifying and reporting suspicious orders at that point in time in 2009?

A. Yes.

Q. Did Ms. Boockholdt and her colleagues request particular policies to review as you described the system?

A. Yes, she did.

Q. And did you provide those to her?

A. Yes.

Q. Were copies provided or she just reviewed them?

A. She reviewed them. And where, where she requested information, we prepared them. And the ones that were not readily available, to the best of my recollection, were put on a thumb drive and mailed to her.

Q. Did you show her the reports that the SOM system generated?

A. I did.

Q. Mr. Mone, were you transparent with the DEA about the way Cardinal's SOM system worked?

A. Yes, very.

Q. Did you hold anything back?

A. No.

Q. In that early 2009 meeting with Ms. Boockholdt and her colleagues, did the DEA identify any fault in the way that Cardinal reported suspicious orders?

A. No. Barbara nor the team identified or told us -- if they, if they identified them, they didn't tell us about them. To the best of my knowledge, they didn't identify any.

Q. During your time at Cardinal, were there customers that Cardinal refused to on-board because of a diversion concern?

A. Oh, yes.

Q. During your time at Cardinal, did Cardinal ever terminate customers?

A. Oh, yes.

Q. And when you terminated a customer, did you also notify the DEA?

A. Yes, we did.

Q. Was the DEA aware of the number of suspicious orders reported by Cardinal in the time frame that you were at Cardinal Health?

MR. ACKERMAN: Objection, speculation as to the awareness of the DEA.

THE COURT: Well, do you know the answer to that?

THE WITNESS: Well, what I -- Your Honor, what I can say is that we submitted them to them. What they did with them after we submitted them to them, I don't know.

THE COURT: Okay. Overruled.

BY MS. MAINIGI:

Q. We've talked a bit about the Cardinal policies. As to the implementation of those policies, was the DEA able to see individual customer files?

A. Yes, they were.

Q. Did the DEA visit distribution centers after this early 2009 meeting that you had?

A. Yes, they did, approximately I'd say two months later,

within two months.

Q. Within two months of this early 2009 meeting they visited distribution centers?

A. They did.

Q. Did they tell you they were going to visit?

A. Yes. It was part of the MOA that they were going to conduct on-site visits.

Q. Do you know how many visits they conducted?

A. They, they conducted, to the best of my recollection, all of the ones in the MOA except Swedesboro.

Q. And were there more than the four in the MOA --

A. Yes.

Q. -- that they visited?

A. Correct.

Q. Were they done on different days or all on the same day?

A. All on the same day.

Q. Were you at any of the distribution centers that they conducted a visit to?

A. Yes, I was.

Q. And, to your recollection, what happened at that visit?

A. Well, the, the DEA diversion investigators did a deep dive into the SOM system and wanted it explained as to how the system operated, and wanted to know how the compliance officers and the cage and vault employees were integrated

into the system. And they wanted to see SOM reports and customer due diligence files.

Q. Was it your impression that they were looking to verify the system worked as you had indicated it did?

A. Yes. I think it was a verification visit based upon what Barbara had done for a week to see that it actually did what we said it did.

Q. And in the visits did the DEA request information about particular customers?

A. They did.

Q. Did they review due diligence files for those customers?

A. They did.

Q. To your recollection, did they offer any criticism of the due diligence files during those visits?

A. To the best of my recollection, during the visit I participated in, they made no concerns about the due diligence files that they looked at.

Q. To the best of your recollection, did they offer any comments about how long documentation needed to be held in due diligence files?

A. No, they did not.

Q. To your knowledge, has the DEA ever instructed distributors to maintain information in due diligence files indefinitely?

A. No.

Q. What are DEA cyclical inspections?

A. So as I testified earlier, and I believe that it's a three-year registration, the cyclical inspections are the inspections by DEA within that three-year license window whereby the DEA diversion investigators come in and go through the distribution center.

They go through their records. They go through the cage and vault. They request an audit. You know, they usually have an open inventory that they want to look at and they want to make sure that all of the, you know -- if the computer says that you have 5,000 of X, they want to be able to go onto the shelf and count, and they count up 5,000 of X. So that's what that cyclical inspection looks like.

Q. And during these cyclical inspections by the DEA, did they have full access to Cardinal's policies and procedures?

A. They did.

Q. Full access to files about customers including due diligence?

A. Yes. To the extent that they would ask for them, the team would prepare them and ship them to either the distribution center or directly to the DEA diversion investigator.

Q. Now, as you updated the SOM system over the course of your time in the Anti-Diversion at Cardinal, did you keep

the DEA updated as to any changes or improvements you were making?

A. Yes, I did.

Q. How did you do that?

A. I -- sometimes I would just call Barbara and sometimes I would fly up and show Barbara -- have a meeting with Barbara, you know, schedule a meeting with Barbara, sit down, bring my laptop, open up the laptop, show what we were doing, and have a conversation with Barbara and her team about the improvements. You know, quite frankly, it was a continuous policy improvement process I was proud of.

Q. Did it matter to you what the DEA thought about what you were doing?

A. Yeah, it did, a lot.

Q. Why?

A. Well, you saw my career. I'm a public service guy. This is about a, a -- you know, as I told Mr. Fuller earlier, you know, what you have is a, is a public health crisis. And I firmly believe that it's, it's a process whereby everybody has to participate, you know, within their lane, what they can do to help do the right thing in their lane. And I wanted her to know what we were doing.

And I -- you know, quite frankly, I'd known Barbara for many years and I expected her to tell me -- I expected her to tell me, you know, "Hey, we don't like what you're doing,

change it." And, quite frankly, I would have.

Q. And did you also communicate with various Boards of Pharmacy about what you were doing?

A. Oh, yes.

Q. Did you communicate with the West Virginia Board of Pharmacy about suspicious order monitoring?

A. Yes. I, I -- you went back through my career. As a former Executive Director of the Board, there's kind of a relationship between the Executive Directors. And, so, yes, I communicated not only with the Executive Directors, but when we talked about the MPJE, when the West Virginia Board would send inspectors to the MPJE meeting, I would communicate with them as well there, not just about the MPJE.

Q. To your recollection, did you explain the Cardinal Health Suspicious Order Monitoring System to the West Virginia Board of Pharmacy?

A. To the best of my recollection, I did. They knew the essential parameters of it.

Q. Did they express any concerns to you?

A. No, neither -- none of them did.

Q. And did you tell me earlier that you did -- Cardinal Health did report suspicious orders to the West Virginia Board of Pharmacy as well?

A. Yes, we did.

MS. MAINIGI: Your Honor, I, I continue to reserve my objection on the 2012 settlement. But because Mr. Fuller asked questions about it, I'll ask a couple as well.

THE COURT: All right.

BY MS. MAINIGI:

Q. Describe for me what the 2012 action by DEA against Cardinal Health involved. What facility?

A. It involved the Lakeland facility, Lakeland, Florida facility.

Q. And did it concern specific pharmacies in Florida?

A. It did.

Q. How many?

A. Four.

Q. Now, had Barbara Boockholdt made a recommendation to you for additional due diligence for Cardinal Health customers in Florida?

A. She did.

Q. What was that time period approximately?

A. I don't recall when she, when she asked me to do that.

Q. Did she identify any particular customers?

A. No, she did not.

Q. Now, the pharmacies that dispense controlled substances, they're obviously licensed by the DEA; right?

A. Yes.

Q. And the DEA can certainly take action against

pharmacies; correct?

A. Yes, they can.

Q. When Ms. Boockholdt voiced this concern to you, what did you do?

A. Well, we were in the process -- you know, obviously the investigators would have their, their investigative schedule. And they were scheduled to go down to Florida anyway, and Vince is from Florida.

What we did was we got a team together and we looked at the data. To the best of my recollection, we took like the top 50 customers and sent the whole, the whole team down to Florida to do site visits on, on those Florida customers. She asked me to do it. I did it.

Q. Did you continue doing business with all the customers that you did site inspections on down there?

A. No, we did not.

Q. What was the result of the process?

A. The result of the process was that we determined that there were -- and I don't remember how many. There were pharmacies that based upon the site visit reflected a -- reflected a concern about their corresponding meeting and corresponding responsibility. And, therefore, we made the decision no longer to conduct business with them.

Q. And did the Lakeland action involve some pharmacies that you had already cut off?

A. Yes, they did.

Q. During the time period that you were head of Cardinal's Anti-Diversion system, did you believe that it was effective?

A. Yes, I, I believe it was -- I don't know that you could have very effective, but, yes, it was effective.

Q. Did you believe Cardinal Health complied with DEA regulations and the Controlled Substances Act?

A. Yes, I did.

Q. Now, during your time as the head of Cardinal Health Anti-Diversion Program, did you ever allow an order to be shipped that you believed was going to be used for anything other than a legitimate medical purpose?

A. No.

MS. MAINIGI: I have no further questions.

THE COURT: Is there going to be any cross of Mr. Mone by the other defendants?

MR. HESTER: None from us, Your Honor.

MR. NICHOLAS: No, Your Honor.

THE COURT: How much redirect are you going to have, Mr. Fuller?

MR. FULLER: I hope not much, Judge.

THE COURT: Can you do it in seven minutes?

MR. FULLER: We're sure going to try.

THE COURT: Okay. Let's go.

REDIRECT EXAMINATION

BY MR. FULLER:

Q. Mr. Mone, you said just a moment ago that Ms. Boockholdt under your system pointed out issues in Florida and you went on down there and you found some problems and you cut off pharmacies; right?

A. When -- I missed some of the beginning part of your question.

Q. I'm sorry. When Ms. Mainigi was asking you about Ms. Boockholdt and her telling you about the Florida issue and you said that you guys went down to Florida and you cut off a bunch of pharmacies; right?

A. There, there wasn't a Florida issue per se. What Barbara said was you should -- she was recommending that you go down and look at your Florida customers because of Florida being Florida.

Q. Sure. And your system is the same nationwide, which we've already established, and you cut off a bunch of Florida customers; correct?

A. We cut off customers based upon our site visit review, yes.

Q. It was hundreds of customers, wasn't it?

A. No. We visited, we visited a little more than 50 and we cut off -- I don't remember how many, but we -- as a result of that visit -- as a result of that effort, I